K092076



APR - 2 2010

## 510(k) Summary

### Sponsor

Submitter:
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Contact Person: Robert Schiff
Telephone: 973-227-1830

Date Prepared: June 15, 2009

### Device Name

| | |
|---|---|
| Proprietary Name: | AEGIS & AEGIS II Spinal Systems |
| Common/Usual Name: | Pedicle Screw Spinal System |
| Classification Name: | Pedicle Screw Spinal System per 21 CFR §888.3070<br><br>Spondylolisthesis Spinal Fixation Device System (MNH) per 21 CFR §888.3060<br><br>Spinal Intervertebral Body Fixation Orthosis (KWQ) per 21 CFR §888.3060<br>Class II |
| Classification Code: | MNI, MNH, KWQ |

### Predicate Devices

| | |
|---|---|
| Predicate Device #1: | XIA Spinal System and XIA 4.5 Spinal System (K060361) |
| Predicate Device #2: | XIA Titanium and 4.5 Spinal System (K060979) |
| Predicate Device #3: | GGS Pedicle Screw System (K053573) |
| Predicate Device #4: | U & I, Optima, Spinal System (K031585) |

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## Device Description

The AEGIS® Pedicle Screw System is comprised of pedicle screw with diameters from 4.5mm to 8.5mm with increments of 1mm and length ranging from 20mm to 55 mm with increments of 5mm, a sleeve of standard diameter of 14 mm, and a set screw of M10XP1.0 & rods with standard diameter of 6 mm. All the components are manufactured from medical grade titanium alloy (Ti6Al4V-Eli).

The mono axial pedicle screw is used as an adjunct to spinal fusion surgery, provides a means of gripping a spinal segment. The screws themselves do not fixate the spinal segment, but act as firm anchor points that can then be connected with a rod. The screws are placed at two or three consecutive spine segments (e.g. lumbar segment 4 and 5) and then a short rod is used to connect the screws. This construct prevents motion at the segments that are being fused.

The Corentec® AEGIS II® Spinal system consists of various Pedicle Screws (mono / poly) with standard and guided type designs, Rod and Rod Link with a set screw, the assembly of which is intended to provide temporary stabilization following surgery to fuse the spine. This system is designed on the basis of long standing spinal technology which is already in the market for more than few decades.

## Device Intended Use

The AEGIS and AEGIS II Spinal Systems are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis).

When used as an anterior screw fixation system, The AEGIS I and AEGIS II Spinal Systems are indicated for patients with degenerative disc disease which is defined as back pain of the discogenic origin with degeneration of the disc confirmed by history and radiographic studies, Spondylolisthesis, fracture, spinal stenosis, spinal deformities such as scoliosis, kyphosis, lordosis, tumor, pseudoarthrosis, or revision of failed fusion attempts.

## Materials

All products are made of titanium (Ti-6Al-4V ELI, ASTM F136-98) approved for medical use.

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**Performance Testing**

Mechanical testing performed with the AEGIS and AEGIS II Spinal Systems demonstrated equivalence of the device to legally marketed predicate devices.

Mechanical test reports were completed for the following test methods:

- Static test: Tension, compression and torsion test report (ASTM F1717-04)
- Dynamic test: Fatigue test report (ASTM F1717-04)
- Axial pull-out strength test (ASTM 543-07)
- Axial Gripping Capacity test (ASTM F1798-97)

**Substantial Equivalence**

Corentec Co Ltd. has submitted information to demonstrate that, for the purposes of FDA's regulation of medical devices, the AEGIS and AEGIS II Spinal Systems are substantially equivalent in indications and design principles to predicate devices that have been determined by FDA to be substantially equivalent to pre-amendment devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Corentec Co., Ltd
% Schiff & Company, Inc.
Mr. Robert Schiff
1129 Bloomfield Avenue
West Caldwell, New Jersey 07006

APR - 2 2010

Re: K092076
Trade/Device Name: Aegis and Aegis II Spinal Systems
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, MNH, KWQ
Dated: March 31, 2010
Received: April 1, 2010

Dear Mr. Schiff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

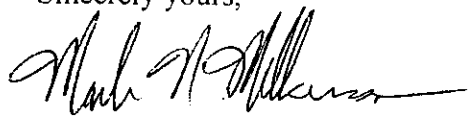
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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# INDICATIONS FOR USE STATEMENT

510(k) Number (if known): Not assigned yet
Device Name: AEGIS and AEGIS II Spinal Systems

Indications for Use:

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**Prescription Use** X **Over-The-Counter Use**_____

(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices